UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
NORTHERN DIVISION

LARRY HALL,
101 Foxfire Drive
Port Deposit, MD 21904
[Cecil County, Maryland]

Civil Action No.:

Plaintiff,

v.

COMPLAINT AND JURY DEMAND

WRIGHT MEDICAL TECHNOLOGY, INC., a Delaware Corporation,
5677 Airline Road
Arlington, TN 38002
[Shelby County, Tennessee]

Serve on Resident Agent:
Corporation Service Company
7 St. Paul Street, Suite 820
Baltimore, MD 21202

Defendant.
_____/

COMPLAINT

COMES NOW Plaintiff LARRY HALL ("Plaintiff"), by and through his undersigned counsel, hereby sues Defendant WRIGHT MEDICAL TECHNOLOGY, INC. and alleges as follows:

NATURE OF THE ACTION

1. This is an action for strict products liability, negligence, and negligent misrepresentation, and breach of express warranty, breach of implied warranty of fitness for a particular purpose and implied warranty for merchantability for injuries arising out of the Wright Medical Total Hip System. Defendants have known for many years that their hip-replacement device - the Wright Medical Total Hip System with PROFEMUR® Femoral Stem (the

"PROFEMUR® Stem" or "Stem"), PROFEMUR® Neck (the "PROFEMUR® Neck" or "Neck"), CONSERVE® Total Femoral Head (the "CONSERVE® Head" or "Head"), and CONSERVE® Plus Cup (the "CONSERVE® Cup" or "Cup") (collectively referred to as the "Wright Total Hip System" or the "Device") - was prone to fail within a few years of implantation despite the fact that hip implant devices typically last more than 20 years. The Stem and neck of Defendants' Device is comprised of titanium alloy while the Head and Cup of the Device are comprised of a cobalt-chromium alloy.

2. Defendants have known that the cobalt-chromium alloy metal "ball" and "socket" bearings that make up the Wright Total Hip System's hip joint generates metal debris over time that can spread throughout the patient's surrounding bone and tissue.

3. The Wright Total Hip System was prone to fail within a few years of implantation even though hip implant devices typically last more than twenty years. Because of the Wright Total Hip System's defects and Defendants' tortious acts/omissions, Plaintiff LARRY HALL, and many other patients who received these devices, endured unnecessary pain and suffering; debilitating lack of mobility; and subsequent more difficult revision surgeries to replace the faulty Wright Total Hip System, giving rise to greater pain and suffering, a prolonged recovery time, and an increased risk of complications and death from surgery.

4. On July 23, 2009, Plaintiff LARRY HALL received a (1) CONSERVE® PLUS Cup, Shell Size 54mm, cobalt and chromium; (2) CONSERVE® Total A-Class Femoral Head, Diameter, 48mm; (3) PROFEMUR ® Modular Femoral Neck, Short; and, (4) PROFEMUR® TL Stem, Size 3 as part of a left hip total arthroplasty.

5. As a result of the Wright Total Hip System's defects and Defendants' tortious acts/omissions, Plaintiff, and many other patients who received these Wright Total Hip Systems,

endured unnecessary pain and suffering; debilitating lack of mobility; and subsequent surgeries to replace the faulty Wright Total Hip System and address complications arising from the Wright Total Hip System and revision surgeries, giving rise to more pain and suffering, a prolonged recovery time, and an increased risk of complications and death from surgery.

6. Plaintiff, and those like him, have suffered from unnecessary pain, debilitation, hospitalization, and the need to undergo subsequent revision surgeries because Defendants defectively designed the Wright Total Hip System and/or failed to adequately warn of the dangers of the Wright Total Hip System.

7. On and prior to July 23, 2009, Defendants knew or should have known, based on hundreds of reports received from orthopedic surgeons around the U.S. that the Wright Total Hip System was defective and likely to fail. Defendants concealed this adverse information and continued to represent to Plaintiff LARRY HALL, Plaintiff's healthcare providers and the public that the Wright Total Hip System was a safe, effective medical device with a low failure rate.

8. Subsequent to the implantation of the Wright Total Hip System in the left hip, LARRY HALL experienced the painful effects of the product's defective design and manufacture. LARRY HALL suffered persistent pain, swelling, elevated metal ions, pseudotumor, and discomfort, all worsening. While Plaintiff's physicians searched for the cause of LARRY HALL's pain, LARRY HALL continued to endure persistent pain, swelling, pseudotumor, and discomfort. LARRY HALL suffered emotional distress because of the defective product. LARRY HALL had to undergo major revision surgery to remove and replace the defective Wright Total Hip System.

9. Revision surgery to remove the failed Wright Total Hip System and replace with a new implant is a complex, risky and painful procedure. Revision surgeries are generally more complex than the original hip replacement as there is less bone available to attach the new implant. Revision surgeries also are usually longer than the original hip replacement procedure and have a higher rate of complications.

10. On July 11, 2017, LARRY HALL underwent an extensive revision surgery of his failed left total hip arthroplasty.

PARTIES

11. Plaintiff LARRY HALL, at all times relevant hereto, was a resident of Port Deposit, Cecil County, Maryland.

12. Defendant Wright Medical Technology, Inc., is a Delaware corporation with its principal place of business at 5677 Airline Road, Arlington, Tennessee 38002, and as such is a citizen of the State of Delaware and is a citizen of the State of Tennessee.

13. Defendant Wright Medical Technology, Inc., does business in Cecil County, Maryland, and is registered to do business in the State of Maryland. Corporation Service Company, 7 St. Paul Street, Suite 820, Baltimore, MD 21202 is the Registered Agent of Defendant Wright Medical Technology, Inc., for service of process in the State of Maryland.

14. At all times relevant hereto, Defendant Wright Medical Technology, Inc. was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous prosthetic orthopedic products, including the Wright Total Hip System.

15. Defendants Wright Medical Technology, Inc. are collectively referred to as Defendants "Wright" or "Defendants Wright." At all times relevant herein, each of the Defendants Wright were the representatives, agents, employees, co-conspirators, servants, employees, partners, joint-venturers, franchisees, or alter egos of the other Defendants Wright and was acting within the scope of its respective authority by virtue of those interrelationships.

16. The various prosthetic orthopedic products of Defendants Wright were marketed, distributed, and sold by the Defendants Wright to hospitals, orthopedic surgeons, and consumers in Cecil County, Maryland.

JURISDICTION AND VENUE

17. This Court has jurisdiction over Defendants and this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendants and because the amount in controversy between Plaintiff and Defendants exceeds $75,000, exclusive of interest and cost, and because, among other reasons, Defendants have significant contracts with this District by virtue of doing business within this judicial District.

18. Venue in this action properly lies within this District pursuant to 28 U.S.C. § 1391 because Defendants reside in this District and because a substantial part of the acts and/or omissions giving rise to these claims occurred within this District.

19. Assignment to the Northern Division is proper under 28 U.S.C. § 100(1).

FACTUAL BACKGROUND – THE CONSERVE® SYSTEM

20. The hip joint is where the femur connects to the pelvis. This joint is made up of the femoral head - a ball-shaped bone at the top of the femur - and the acetabulum - a cup- shaped bone at the bottom of the pelvis, in which the femoral head rotates. In a healthy hip joint, the femur and the acetabulum are strong and the rotation of the bones against each other is cushioned and

lubricated by cartilage and synovial fluid.

21. A total hip replacement replaces the body's natural hip joint with an artificial one, usually made out of metal and/or ceramic and plastic. A total hip replacement system generally includes four components: a femoral stem, a femoral head, a liner, and an acetabular shell. After the surgeon hollows out a patient's femur bone, the femoral stem is ·implanted. The femoral head is a metal ball that is fixed on top of the femoral stem. The femoral head forms the hip joint when it is placed inside the liner and acetabular shell. These conventional hip replacement prostheses typically last 15 to 20 years.

22. The Wright Medical CONSERVE® Hip System has a different and defective design, one that puts a larger "big femoral head" metal ball directly in contact with a metal acetabular monoblock cup when most other hip replacements use a modular polyethylene or plastic acetabular cup or a polyethylene or plastic liner in the acetabular cup. By using a metal acetabular cup and a large metal femoral ball, the Wright Total Hip System creates greater torque and forces metal to rub against metal with the full weight and pressure of the human body.

23. Despite its unorthodox design, Defendants did not properly test the CONSERVE® Hip System for safety, efficacy and durability. Other metal-on-metal (hereinafter "MOM") prosthetic hip device manufacturers carefully screen, select and train orthopedic surgeons on proper implant procedures for their respective devices. However, Defendants aggressively marketed, promoted and encouraged orthopedic surgeons in the U.S. to use the CONSERVE® System without screening, selecting, or training the surgeons on how to implant the CONSERVE® System.

FACTUAL BACKGROUND - THE WRIGHT TOTAL HIP SYSTEM

24. The Wright Total Hip System comprises separate femoral stem and neck components and offers a variety of sizing options intra-operatively. The benefit, according to Defendants, was that by allowing the surgeon to independently manage leg length, neck version, and femoral offset, the Wright Total Hip System provides surgeons the ability to better personalize the biomechanics of a patient's hip replacement.

25. The Wright Total Hip System can be used interchangeably with many bearing surface components (which comprise the ball and acetabular cup or socket). The bearing surface system or components are unrelated to the Wright Total Hip System's method of failure.

26. Despite its unorthodox design, Defendants did not properly test the Wright Total Hip System for safety, efficacy and durability. Other metal-on-metal (hereinafter "MOM") prosthetic hip device manufacturers carefully screen, select and train orthopedic surgeons on proper implant procedures for their respective devices. However, Defendants aggressively marketed, promoted and encouraged orthopedic surgeons in the U.S. to use the Wright Total Hip System without screening, selecting, or training the surgeons on how to implant the Wright Total Hip System.

HISTORY

27. In December 1999, the WRIGHT acquired a European manufacturer of artificial hip devices known as Cremascoli Ortho ("Cremascoli"), which had designed and manufactured artificial hips with a modular neck component since approximately 1985.

28. Sometime after acquisition of Cremascoli, WRIGHT re-branded the Cremascoli artificial hip modular neck product line, and a compatible artificial hip stem, as the Wright Total Hip System.

29. Sometime after December 13, 2000, WRIGHT began to manufacture, label and, both directly and indirectly, including through distributor PERI PROCTOR, market, promote, distribute and sell in the United States the Wright Total Hip System and its components, including the Head, Cup and Neck components.

30. In the year 2000, and in all years thereafter to the present, cobalt-chromium was also an alloy generally available for use in manufacturing implantable medical devices, and in fact was used by WRIGHT in their manufacturing of certain components for use in WRIGHT artificial hips, including the CONSERVE® Head and the CONSERVE® Cup components.

31. While Defendant WRIGHT wanted to market its Wright Total Hip System in the U.S., it did not want to endure the long and expensive FDA approval process. Instead, WRIGHT exploited a loophole in FDA regulations that would allow its device to enter the U.S. market without proper testing or approval. WRIGHT represented that the Wright Total Hip System design was substantially equivalent to other hip replacement products already on the market.

32. While representing to the FDA that it's Wright CONSERVE® System was "substantially equivalent" to other hip replacement products, WRIGHT omitted the Wright Total Hip System's critical distinguishing features. The Wright Total Hip System's femoral head has a circumference larger than industry standard. Also, the acetabular cup departs from industry standards in that it (1) is thinner; (2) has a smaller circumference; (3) is double-heat treated rather than single-heat treated; (4) has an exterior shell that lacks reliable bone ingrowth materials; (5) offers no obvious means of fixation other than the expectation that the patient's bone will grow into the porous exterior of the cup; and (6) has a low clearance which spreads the contact area out closer to the edge of the cup resulting in increased friction from the lack of lubrication entering the cup.

33. Shortly after the U.S. launch of the CONSERVE® System, Defendants received hundreds of complaints from doctors reporting failures. By 2010, Defendants had received hundreds of such reports regarding their PROFEMUR® and CONSERVE® lines. Defendants failed to disclose, or actively concealed, these adverse reports from doctors and patients, including Plaintiff PAUL POHL and Plaintiff's surgeon, and continued to promote the Wright Total Hip System as a safe and effective device.

34. Defendants had a strong monetary motive not to reveal the dangers associated with the Wright Total Hip System. In 2010 alone, WRIGHT's sales revenue was over $518 million, with about $176 million comprising of sales from their hip products, making it one of the most profitable groups.

WRIGHT MEDICAL "PHASES OUT" ITS TITANIUM MODULAR NECKS AND REPLACES THE TITANIUM WITH COBALT CHROMIUM

35. After realizing that the PROFEMUR® long titanium necks would catastrophically fail the ASTM F 2068-03 standard, Wright Medical decided to phase out the PROFEMUR® Modular Necks made with titanium and replace them with a cobalt-chrome alloy.

36. On or after August 25, 2009, WRIGHT began distributing in the United States PROFEMUR® modular necks made of a CoCr alloy.

37. On or after August 25, 2009, Wright Medical changed PROFEMUR® Modular Necks to the cobalt-chrome alloy, yet, issued no warnings or modifications.

38. While Defendant WRIGHT wanted to market its PROFEMUR® Neck in the United States, it did not want to endure the long and expensive FDA approval process. Instead, WRIGHT exploited a loophole in FDA regulations that would allow its device to enter the United States market without proper testing or approval. WRIGHT represented that the PROFEMUR® Neck design was substantially equivalent to other hip replacement products

already on the market.

39. While representing to the FDA that the PROFEMUR® Neck was "substantially equivalent" to other hip replacement products, WRIGHT omitted the Wright Total Hip System's critical distinguishing features.

40. PROFEMUR® Modular Necks distributed in the United States made of cobalt chrome are made in the same six long versions, and the same six short versions, as the six long and six short versions of the PROFEMUR® Titanium Modular Necks.

41. PROFEMUR® Modular Necks distributed in the United States made of cobalt chrome have the same dimensions as the trunnion, and at the oblong taper, as PROFEMUR® Titanium Modular Necks, making them compatible for assembly with the same Wright Medical femoral heads and hips stems that the PROFEMUR® Titanium Modular Necks were compatible with.

DEFECTIVE METAL-ON-METAL DESIGN

42. Defendants have known for years that implementation of the CONSERVE® and Wright Total Hip Systems of the Wright Total Hip System results in metallosis, biological toxicity, and an increased risk for early and excessive premature failures of the Wright Total Hip System.

43. Implantation of the CONSERVE® System in congruence with the Wright Total Hip System results in the release of high levels of toxic metal ions into hip implant patients' tissues and bloodstreams. Particles released by friction of the metal-on-metal surfaces also results in metallosis, tissue death, and tumor growth. This friction wear is especially pronounced in the early "wear in" period, especially on the leading edge of the metal acetabular Cup. In the hip implant industry, this is commonly referred to as "edge wear" or "edge loading."

44. Particles released by friction of the metal-on-metal surfaces results in metallosis, tissue death, and tumor growth. This friction wear is especially noticed on the modular head-neck and neck-stem junctions.

45. The Wright Total Hip System is defective because proper and successful surgical placement is exceedingly difficult for even experienced and competent surgeons to accomplish in implanting the Wright Total Hip System in patients.

46. Once the body is exposed to the CONSERVE® and PROFEMUR® application of the Wright Total Hip System and absorbs the toxic metallic ions and particulate debris created by friction of the metal-on-metal and modular surfaces, inflammation occurs which leads to severe pain, infection, death of the surrounding tissue, bone loss, and the potential for tumors to develop. Since 2006, Defendants have had actual knowledge that the CONSERVE® System would fail early due to metal debris, thereby giving rise to unnecessary pain and suffering, debilitation, and the need for revision surgery to replace the defective devices with the attendant risk of complications and death from such further implant revision surgery in patients, including Plaintiff.

47. The fact that the Wright Total Hip System with the CONSERVE® and Wright Total Hip Systems fail prematurely and thereby gives rise to unnecessary pain and suffering, debilitation, and the need for revision surgery for implanted patients is a material fact.

48. Defendants failed to disclose this material fact to consumers, including Plaintiff and Plaintiff's implanting physician.

CONSERVE® RELIANCE

49. Instead, Defendants took affirmative steps to prevent physicians and consumers, including, but not limited to, Plaintiff, from learning of this material fact, while aggressively

marketing the Wright Total Hip System and CONSERVE® Cup as safe and effective for use in hip replacement surgeries. This concealment was made with the intent to induce Plaintiff, as well as other patients and physicians, to purchase the Wright Total Hip System and the CONSERVE® Cup and to prevent patients from discovering they were implanted with a defective device and from filing lawsuits seeking damages.

50. Plaintiff and Plaintiff's physicians would have been able to discover the cause of his pain and disability or defects in the Wright Total Hip System earlier, but for the fact that Defendants actively concealed these facts from physicians, patients, and Plaintiff, which led to a delay in discovery as well as unnecessary suffering for Plaintiff.

51. In reliance on Defendants' fraudulent concealment of material fact, Plaintiff's implanting surgeon, selected, and Plaintiff purchased the Wright Total Hip System so that plaintiff's physician could surgically implant the Wright Total Hip System into plaintiff's body. Had Plaintiff's surgeon known that the Wright Total Hip System would fail early, thereby giving rise to unnecessary physical injury, pain and suffering, debilitation, and the need for revision surgery to replace the Wright Total Hip System with the attendant risk of complications and death from such further surgery, Plaintiff's implanting surgeon would not have selected the Wright Total Hip System for implantation into Plaintiff. Had Plaintiff known that the Wright Total Hip System would fail early, thereby giving rise to unnecessary physical injury, pain and suffering, debilitation, and the need for revision surgery to replace the Wright Total Hip System with the attendant risk of complications and death from such further surgery, Plaintiff would not have purchased the Wright Total Hip System.

52. Defendants made representations, affirmations of fact, and/or promises through their advertisements, labeling, detailing, marketing, and/or promotion of the Wright Total Hip

System to healthcare professionals, the FDA, Plaintiff, and the public by representing that the induce patients and surgeons to purchase or use the Wright Total Hip System with the CONSERVE® Cup.

53. These representations, affirmations, and/or promises regarding the Wright Total Hip System were false. These representations, affirmations, and/or promises also constitute express warranties that the Wright Total Hip System with the CONSERVE® Cup component conform to those representations.

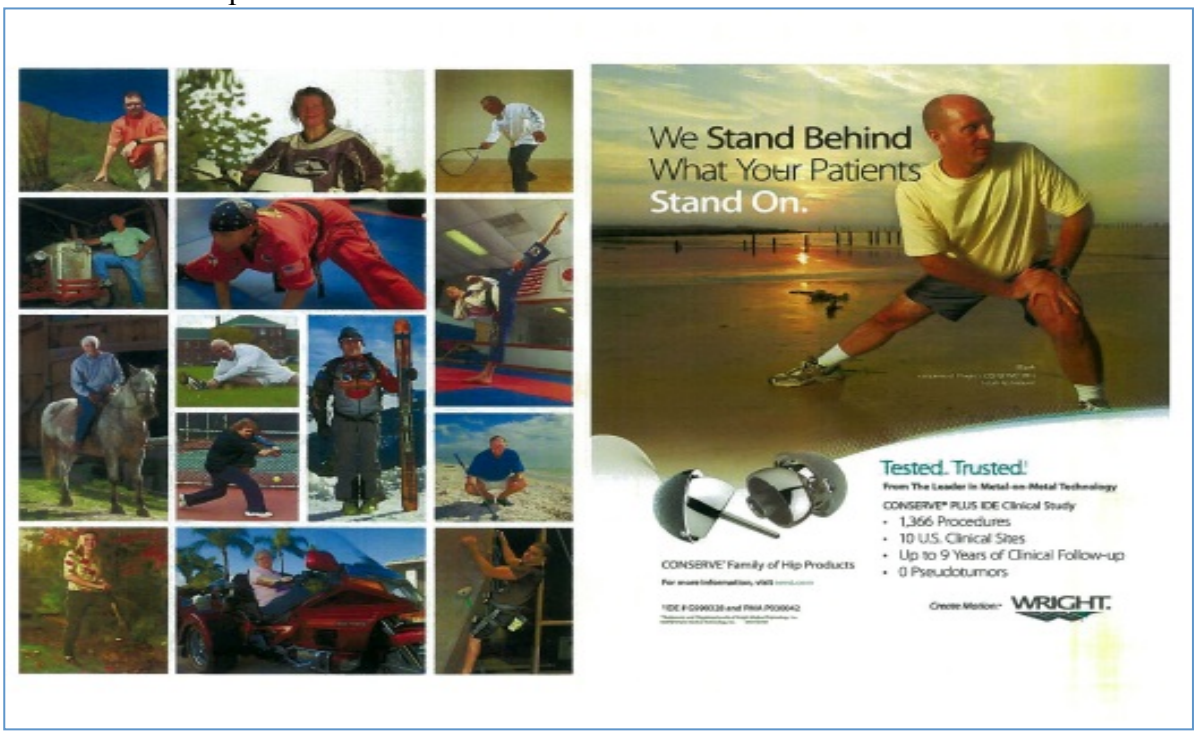
54. Plaintiff was in privity with WRIGHT through Plaintiff's surgeon, acting as an agent, and relied on WRIGHT's express warranties and/or representations in choosing to purchase the Wright Total Hip System with CONSERVE® Cup component.

55. Defendants utilized misrepresentations that contradicted their own knowledge regarding activity levels and metal ions to drive sales of the CONSERVE® System. Despite knowing that increased activity would lead to increased wear, Defendants directed their marketing (via websites, journal ads, brochures, pamphlets, patient testimonials, endorsements, newspaper articles and other PR) aimed at surgeons and younger, more active consumers who wanted to return to the following strenuous physical activities, including but not limited to:

a. Surfing;
b. Yoga;
c. Skiing;
d. Martial Arts, including competition levels;
e. Hockey;
f. Ice skating;
g. Motorcycling;
h. Horseback rides;
i. Tennis;
j. Golf;
k. Soccer;
l. Football;
m. Mountain climbing;
n. Running, including marathons and triathlons;

o. Hiking;
p. Biking, including trail riding;
q. Swimming;
r. Racquetball;
s. Active military duty;
t. Competitive wrestling; and
u. Kayaking.

56. Representative of these ads include:



57. No later than 2003, WRIGHT recognized that, "metallic particulate debris is approximately an order of magnitude smaller than PE debris, thus even low rates of volumetric wear can lead to large numbers of particles." *Metal-Metal: Metal Ions – A Cause for Concern in Metal Bearings!*, presentation by John J. Jacobs, M.D.

58. Before, during and since WRIGHT designed developed, manufactured, marketed, and sold its CONSERVE® Systems, WRIGHT knew patients with CONSERVE® metal on metal hip implants exhibited 10 times higher concentrations of metal ions compared to patients with metal on poly hip implants.

59. When marketing the CONSERVE® Systems, WRIGHT worked to overcome a critical concern for metal-on-metal hip devices, i.e., metal ion release. Thus, as part of its marketing strategy to "de-criminalize metal ions" and drive sales, WRIGHT instructed its sales personnel, contrary to its own knowledge, that the effects of metal ion release are known and have been demonstrated to be safe and had surgeon consultants promote that its A-Class metal reduced wear and generated fewer metal ions.

60. WRIGHT promoted the decriminalization of metal ions through consulting surgeon Key Opinion Leaders' ("KOL") presentations to orthopaedic groups, paid-for scientific data publications, celebrity endorsements, and sales representative training, among other avenues.

61. Defendants utilized taglines such as "Reduced Wear, Increased Longevity," "A-Class Never Compromise," and "A Hip For Life" in marketing its A-Class BFH technology with the Conserve Total Hip Device.

62. Defendants have never reported the CONSERVE® System's high failure rates to surgeons, to patients with implanted CONSERVE® Systems, or to the public.

63. Upon information and belief, WRIGHT received complaints and reports of unacceptable failure rates of its CONSERVE® Systems from Brad Penenberg, M.D., a Wright KOL, consultant, Fab Four member, Peer-to-Peer trainer, premier Los Angeles surgeon and CONSERVE® royalty recipient, who concluded the CONSERVE® was not a successful product and stopped using them because of problems he experienced with the CONSERVE® starting in 2007.

64. Defendants knew their representations were false or made these representations recklessly, knowing that they lacked sufficient knowledge upon which to base such representations.

65. Defendants made these representations for the purpose of inducing orthopaedic surgeons, including Plaintiff's implanting surgeon, and patients like Plaintiff to act upon the representations and select the CONSERVE® as part of the Wright Hip Implant System for implantation.

66. WRIGHT advertised on its website and in its product brochures that were distributed to physicians and patients as early as September of 2004 that Wright's Total Hip System with CONSERVE® Cup was designed to be an improvement over the metal-on-polyethylene implants because the metal-on-metal design would reduce the amount of wear particles.

67. In particular, Defendants' advertisements and representations included this statement:

> Despite improvements in the manufacturing, processing, and sterilization of polyethylene, wear related problems still exist in modem total hip arthroplasty. To address this problem, the CONSERVE® Total Hip System has eliminated polyethylene from the design altogether. The result is a one-piece, highly super finished metal-on-metal design, which provides significantly less wear particles than the conventional total hip replacement.

68. Defendants' advertisements and representations also included misleading information that would lead both patients and their surgeons to believe there would only be a minimal amount of wear debris generated from the CONSERVE® Cup in that the amount of wear debris would be substantially less than that associated with ceramic-on-polyethylene or cobalt chrome- on-polyethylene implant designs.

69. Plaintiff's physicians communicated Defendants' representations to plaintiff. These representations about the extended durability of the Wright Total Hip System with CONSERVE® Cup led Plaintiff and Plaintiff's surgeon to believe that the Wright Total Hip System with a CONSERVE® Cup component would last longer than the approximate 15 to 20 years that a conventional hip implant would last.

70. Defendants knew that the Wright Total Hip System with CONSERVE® Cup would fail prematurely due to metal debris, thereby giving rise to unnecessary pain and suffering for patients, debilitation, and the need for revision surgery to replace the defective Wright Total Hip System, yet, at the same time, Defendants were representing to patients and surgeons, including Plaintiff, that the Wright Total Hip System with CONSERVE® Cup component has fewer potential safety risks than other implant models and designs.

PROFEMUR® RELIANCE

71. Since the 1980's medical and scientific literature has reported corrosion to be a problem when titanium and cobalt chromium alloys have been used at modular junctions.

72. Medical literature published in 2009 by a competing manufacturer indicates that development of CoCr neck components was discontinued due to a five-fold increase in wear debris of the Ti6Al4V neck when coupled with a CoCr femoral head. However, in its marketing and sale of the PROFEMUR® Neck, Defendant WRIGHT represented and warranted that its proprietary materials alleviated this problem.

73. In various marketing and promotional material published and distributed by WRIGHT from the year 2002, and into the year 2010, and available to WRIGHT's sales representatives and distributors, surgeons, patients, and the general public, WRIGHT made representations, statements, and claims about its CONSERVE® and PROFEMUR® hip

product lines that these products were intended for patients who wanted to return to an active lifestyle.

74. Despite Defendant WRIGHT's claims, the material combination of CoCr and Ti6A14V has been reported to cause fretting, galvanization and corrosion.

75. Prior to being implanted with the PROFEMUR® Neck, Defendants knew or should have known that combining the PROFEMUR® Neck with the PROFEMUR® Stem would fail prematurely and cause serious post-implant complications for patients, including Plaintiff. Complications arising out of the implantation of the PROFEMUR® Neck into the CONSERVE® femoral head that Defendants knew or reasonably should have known of, included, but were not limited to, bone cysts; pseudotumors; metallosis and osteolysis; high levels of metal ions, such as chromium and cobalt, in the bloodstream; detachment, disconnection and/or loosening of the acetabular cup; loosening of the femoral component; and other complications requiring revision surgery. Armed with such knowledge, Defendants concealed the true risks of the PROFEMUR® Neck and instead continued to market, defend and promote the Wright Total Hip System.

76. Despite legal and moral obligations to cease promoting, marketing, selling and defending the Wright Total Hip System upon awareness of its serious risks, Defendants did not notify physicians, including Plaintiff's surgeons, of the Wright Total Hip System's propensity to fail and cause other serious complications.

77. Once the body is exposed to the Ti6Al4V alloy PROFEMUR® Neck and CoCr CONSERVE® femoral head of the Wright Total Hip System, the hip joint absorbs the toxic metallic ions and particulate debris created by friction of the metal-on-metal surfaces. As a result, inflammation occurs which leads to severe pain, infection, death of the surrounding tissue,

bone loss, and the potential for tumors to develop. Since the early 1980s, Defendants have had actual knowledge that the combination of CoCr femoral heads with Ti6Al4V modular necks would fail early due to metal debris, thereby giving rise to unnecessary pain and suffering, debilitation, and the need for revision surgery to replace the defective devices with the attendant risk of complications and death from such further implant revision surgery in patients, including Plaintiff.

78. The fact that the Wright Total Hip System fails prematurely and thereby gives rise to unnecessary pain and suffering, debilitation, and the need for revision surgery for implanted patients is a material fact.

79. Defendants failed to disclose this material fact to consumers, including Plaintiff and Plaintiff's physician.

LARRY HALL'S WRIGHT TOTAL HIP SYSTEM

80. On July 23, 2009, Plaintiff LARRY HALL underwent a left hip surgery performed by Dr. Andrew Michael Cumiskey, MD at Union Hospital in Elkton, Maryland in Cecil County. At the time of these procedures, the Wright Total Hip System manufactured, designed, distributed and warranted by Defendants was implanted into Plaintiff LARRY HALL. Plaintiff LARRY HALL's surgeons, medical staff, and other healthcare providers met or exceeded the standard of care applicable to the hip replacement surgery. The Wright Total Hip System subsequently failed on the left hip.

81. Upon information and belief, Defendants designed, manufactured, distributed, and sold in the United States various prosthetic orthopedic devices, including the hip prosthesis system in issue, the Wright Medical Total Hip System, and including the following components:

a. CONSERVE® PLUS Cup, Shell Size 54mm, cobalt and chromium;

b. CONSERVE® Total A-Class Femoral Head, Diameter, 48mm;

c. Wright Modular Femoral Neck, Size: Short; and,

d. PROFEMUR® TL Stem, Size 3.

These components shall hereinafter be collectively referred to as the Wright Total Hip System.

82. The Wright Total Hip System in issue and its various components were sold in the United States by virtue of one or more 510(k) Premarket Notice procedures filed with the United States Food and Drug Administration by Defendants.

83. At the time the Wright Total Hip System was implanted in the Plaintiff it was in the same condition in all relevant respects as when it left the Defendants control.

84. The Wright Total Hip System and the components implanted in the Plaintiff were and are unreasonably dangerous for their intended and/or reasonably foreseeable uses in that:

a. They were and are unreasonably dangerous under the risk-benefit test as a result of one or more, or a combination of, the following conditions:

(1) The neck was manufactured in such a manner as to be subjected to bending, thereby increasing the potential for failure;

(2) The surface of the section of the neck that was inserted into the femoral stem was manufactured in such a manner as to increase the potential for fretting and corrosion and failure;

(3) The portion of the neck that was inserted in the femoral stem was in a narrow, confined space, thereby increasing the potential for fretting, corrosion and failure;

(4) The components were manufactured in such a way as to make the modular neck component susceptible to fretting and corrosion, thereby increasing the potential for failure;

(5) The components were manufactured in such a way as to make the modular neck component susceptible to fatigue fractures; and

(6) There may be other conditions or defects yet to be determined.

85. As a direct and proximate result of the design, manufacture and composition of the Wright Total Hip System, LARRY HALL's Wright Total Hip System created metallic debris. The Wright Total Hip System forced LARRY HALL to live with debilitating pain, swelling, discomfort, and emotional distress.

86. On July 11, 2017, Plaintiff LARRY HALL underwent left hip revision surgery at University of Maryland St. Joseph Medical Center in Towson, Maryland. Dr. Brian David Mulliken performed the revision due to metallosis and synovial fluid around the hip replacement.

87. Defendants recklessly, knowingly, intentionally and fraudulently misrepresented to the medical community and the general public, including Plaintiff LARRY HALL and his healthcare providers, that the Wright Total Hip System was safe and effective for its intended use.

88. Defendants recklessly, knowingly, intentionally and fraudulently concealed and suppressed adverse information relating to the safety and performance of the Wright Total Hip System from the medical community and the general public, including Plaintiff LARRY HALL and his healthcare providers.

89. Defendants' misrepresentations were communicated to the medical community and the general public, including Plaintiff LARRY HALL and his healthcare providers, who would rely on such in selecting the Wright Total Hip System.

90. Specifically, Defendants misrepresented and actively concealed material facts regarding the safety and performance of the Wright Total Hip System including, but not limited to:

a) the Wright Total Hip System was not as safe as other available hip

devices;

b) the Wright Total Hip System has an unacceptably high rate of failures requiring revision surgery;

c) the safety and performance of the Wright Total Hip System was not adequately tested and/or known by Defendants;

d) patients implanted with the Wright Total Hip System were at increased risk of experiencing painful and debilitating product failure and were more likely to undergo revision surgery than patients using other hip implant devices;

e) the Wright Total Hip System was designed, manufactured, marketed, promoted, distributed and sold negligently, defectively and/or improperly;

f) the design of the Wright Total Hip System increased the wear between the femoral component, as compared to other hip implant products;

g) metal corrosion was more likely to occur, and would occur with greater severity, as compared to other hip replacement products;

h) surgical implantation according to recommended specifications was substantially more difficult than other hip replacement products, and proper surgical implantation was substantially less likely to occur;

i) metal ion debris would be released into the patient's body; and

j) safer alternatives were available.

91. To Plaintiff's detriment, LARRY HALL and his healthcare providers justifiably relied on and/or were induced by Defendants' misrepresentations and/or active concealment to

recommend, purchase, implant and/or use the Wright Total Hip System.

92. As a direct, legal, proximate and producing result of Defendants' misrepresentation and active concealment of material facts, Plaintiff LARRY HALL was injured.

93. Plaintiff was prevented from discovering this information because Defendants misrepresented, and continue to misrepresent, to the public and to the medical profession that Wright Total Hip System has no propensity to fail or cause other serious complications, and Defendants have fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

94. Plaintiff LARRY HALL would not have used the Wright Total Hip System had Defendants properly disclosed the risks associated with the implants.

FIRST CAUSE OF ACTION
STRICT PRODUCTS LIABILITY FAILURE TO WARN

95. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs 1-93 and further alleges as follows:

96. At all times relevant herein, Defendants were engaged in the design, development, testing, manufacturing, distribution, marketing, promoting and/or sale of the Wright Total Hip System.

97. Defendants designed, manufactured, assembled, distributed, marketed, promoted and sold the Wright Total Hip System to medical professionals and patients knowing they would then be implanted in patients needing hip prosthesis.

98. Defendants distributed and sold the Wright Total Hip System in their original form of manufacture, which included the defects described herein.

99. The Wright Total Hip System was expected to and reached Plaintiff LARRY HALL and his implanting surgeon in the State of Maryland without substantial change or adjustment in its condition as manufactured and sold by Defendants.

100. The Wright Total Hip System designed, developed, tested, manufactured, distributed, promoted, marketed and/or sold or otherwise placed into the stream of commerce by Defendants were in a dangerous and defective condition and posed a threat to any user or consumer of the Wright Total Hip System.

101. At all times relevant hereto, Plaintiff LARRY HALL was a person the Defendants should have considered subject to the harm caused by the defective nature of the Wright Total Hip System.

102. The Wright Total Hip System was defective and unreasonably dangerous when it left the possession of Defendants because it contained warnings insufficient to alert the medical community and patients, including Plaintiff LARRY HALL and his healthcare providers, to the dangerous risks associated with the Wright Total Hip System when used for its intended and reasonable foreseeable purpose. The dangers and risks included, but were not limited to, a tendency to (a) detach, disconnect and/or loosen; (b) generate dangerous and harmful metal debris in the patient's body; (c) corrode; (d) cause pain; (e) inhibit mobility and (f) require revision surgery.

103. At all times relevant hereto, Plaintiff LARRY HALL and his healthcare providers used the Wright Total Hip System for its intended or reasonably foreseeable purpose.

104. Plaintiff LARRY HALL and his healthcare providers could have discovered no defect in the Wright Total Hip System through exercising due care.

105. Defendants knew or should have known, by scientific knowledge available

before, at and after the time of manufacture, distribution and sale of the Wright Total Hip System, of potential risks and side effects associated with the Wright Total Hip System. Defendants knew or should have known of the defective condition, characteristics, and risks associated with the said product, as previously set forth herein.

106. The warnings and instructions provided with the Wright Total Hip System by Defendants did not adequately warn of the potential risks and side effects of the Wright Total Hip System, which risks were known or scientifically knowable to Defendants.

107. Defendants had a continuing duty to warn the medical community and public, including Plaintiff LARRY HALL and his healthcare providers, of the potential risks and increased failure rate associated with the Wright Total Hip System.

108. Defendants had a duty to warn implanting surgeons and patients such as Plaintiff LARRY HALL, and Defendants breached their duty because they failed to provide adequate and timely warnings or instructions regarding their Wright Total Hip System and their known defects.

109. Defendants, furthermore, breached their duty to warn at pre-surgery and/or post-surgery by (a) failing to adequately communicate the warning to the ultimate users, i.e., Plaintiff LARRY HALL and/or his implanting physician; and/or (b) by failing to provide an adequate warning of the Wright Total Hip System's potential risks.

110. Adequate effort to communicate a warning to the ultimate uses were not made by Defendants and, to the extent a warning was communicated by Defendants, the warning was inadequate.

111. Plaintiff LARRY HALL used the Wright Total Hip System for its intended purpose, i.e., hip replacement.

112. Plaintiff LARRY HALL could not have discovered any defect in the Wright Total Hip System through exercising due care.

113. Defendants, as designers, manufacturers, distributors, promoters, marketers and/ or sellers of medical devices are held to the level of knowledge of experts in their field.

114. Neither Plaintiff LARRY HALL nor his implanting physician had substantially the same knowledge about the Wright Total Hip System as Defendants.

115. As a direct, legal and proximate result of Defendants' failure to adequately communicate a warning and/or failure to provide an adequate warning and other wrongful conduct as set forth herein, Plaintiff LARRY HALL has sustained severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages, as set forth herein.

116. Defendants' failure to adequately warn of the potential risks and side effects of the Wright Total Hip System was a substantial factor in causing Plaintiff LARRY HALL's injuries as set forth above.

WHEREFORE, Plaintiff LARRY HALL demands judgment against the Defendants, in an amount in excess of the minimum jurisdictional limits of this Court, costs and further demands trial by jury.

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY DEFECTIVE DESIGN

117. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs, 1-93, and further alleges as follows:

118. The Defendants had a duty to design and manufacture, and all Defendants had a duty to place into the stream of commerce, distribute, market, promote and sell, the Wright Total

Hip System so it was neither defective nor unreasonably dangerous when put to the use for which it was designed, manufactured, distributed, marketed and sold.

119. At all times relevant hereto, Defendants designed, manufactured, distributed, sold, marketed and/or promoted the Wright Total Hip System, including the (1) PROFEMUR® Stem (Ti6Al4V); (2) PROFEMUR® Neck (Ti6Al4V); (3) CONSERVE® Femoral Head (CoCr) and CONSERVE Cup (CoCr) that was implanted in Plaintiff LARRY HALL's left hip on July 23, 2009.

120. WRIGHT did in fact design and manufacture, while all Defendants were engaged in selling, distributing, supplying and/or promoting the Wright Total Hip System to Plaintiff LARRY HALL and his implanting physician. Defendants expected the Wright Total Hip System they were selling, distributing, supplying, manufacturing and/or promoting to reach, and it did in fact reach, implanting physician and consumers in the State of Maryland, including Plaintiff LARRY HALL and his implanting physician, without substantial change in the condition.

121. At all times relevant hereto, Plaintiff LARRY HALL and his healthcare providers used the Wright Total Hip System for its intended or reasonably foreseeable purpose.

122. At all times relevant hereto, the Wright Total Hip System was dangerous, unsafe and defective in manufacture. Such defects included, but were not limited to, a tendency to (a) detach, disconnect and/or loosen; (b) generate dangerous and harmful metal debris in the patient's body; (c) corrode; (d) cause pain; (e) inhibit mobility; (f) require revision surgery.

123. Defendants knew or should have known of the unreasonably dangerous and serious risks associated with the design of the Wright Total Hip System. Such risks were scientifically knowable to Defendants. However, Defendants performed inadequate evaluation and testing of the Wright Total Hip System design.

124. The Wright Total Hip System manufactured and supplied by WRIGHT and distributed, marketed, promoted and sold by all Defendants, were, therefore, defective in design or formulation in that, when they left the hands of Defendants, the foreseeable risk of harm from the product exceeded or outweighed the benefit or utility of the consumer would expect, and/or it failed to comply with federal requirements for these medical devices.

125. As a direct, legal, proximate and producing result of the defective manufacture of the Wright Total Hip System, Plaintiff LARRY HALL was injured.

126. Defendants' dangerous design and failure to adequately test the safety of the Wright Total Hip System was a substantial factor in causing Plaintiff LARRY HALL's injuries.

WHEREFORE, Plaintiff LARRY HALL demands judgment against the Defendants, in an amount in excess of the minimum jurisdictional limits of this Court, costs and further demands trial by jury.

THIRD CAUSE OF ACTION
STRICT PRODUCTS LIABILITY MANUFACTURING DEFECT

127. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs, 1-93, and further alleges as follows:

128. Defendants Wright are the manufacturers, designers, distributors, sellers, and/or suppliers of orthopedic devices including the Wright Total Hip System devices and its components.

129. The Wright Total Hip System devices manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants Wright, were defective in their manufacture and construction when they left the hands of Defendants Wright, in that they deviated from product specifications and/or applicable federal requirements for these medical devices, posing a serious risk of injury.

130. As a direct and proximate result of Plaintiff's use of Defendants' Wright Total Hip System devices, as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants Wright and/or the failure of these Defendants to comply with federal regulations, Plaintiff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

131. As a direct and proximate result of Defendants Wright's conduct as set forth herein Plaintiff has suffered, and will continue to suffer injuries, damages and losses in an amount to be determined by the trier of fact.

WHEREFORE, Plaintiff LARRY HALL demands judgment against the Defendants, in an amount in excess of the minimum jurisdictional limits of this Court, costs and further demands trial by jury.

FOURTH CAUSE OF ACTION
NEGLIGENCE

132. Plaintiff hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs, 1-93, and further alleges as follows:

133. At all times relevant hereto, Defendants designed, manufactured, distributed, sold, marketed and/or promoted the Wright Total Hip System for implantation into customers, such as LARRY HALL, by physicians, surgeons and health care providers in the U.S.

134. At all times relevant hereto, Defendants knew or should have known that the novel design of the Wright Total Hip System necessitated clinical trials and other pre-marketing evaluations of risk and efficacy. Such testing would have revealed the increased risk of failure and complications associated with the Wright Total Hip System. A reasonable manufacturer under the same or similar circumstances would have conducted additional testing and evaluation of the Wright Total Hip System's safety and performance prior to placing the

Wright Total Hip System into the stream of commerce.

135. At all times relevant hereto, Defendants knew or should have known of the serious complications and high failure rate associated with the Wright Total Hip System. Despite receiving hundreds of reports of serious complications from healthcare providers, Defendants chose (1) not to perform any additional testing of the Wright Total Hip System; (2) not to investigate other potential causes of the reported complications; (3) not to suspend sales or distribution; or (4) not to warn physicians and patients of the propensity of the Wright Total Hip System to detach, disconnect and/or loosen from a patient's acetabulum; generate dangerous and harmful metal debris in the patient's body; cause pain; inhibit mobility; and/or require revision surgery.

136. Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, warning, marketing, promotions and distribution of the Wright Total Hip System because they knew or should have known these products caused significant bodily harm and were not safe for use by consumers, and/or through failure to comply with federal requirements.

137. WRIGHT was negligent in designing and manufacturing the CoCr alloy PROFEMUR® Neck such that it caused metal-on-metal wear between the modular neck and femoral stem components of the Wright Total Hip System, increased metallic corrosion, and caused serious side effects, including; but not limited to, severe pain and disability, metallosis, synovitis, bone loss, tissue necrosis, premature device failure, the need for revision surgery, and death.

138. Prior to and when Plaintiff LARRY HALL's surgeon performed implantation surgery on July 23, 2009, Defendants knew or should have known that the Wright Total Hip

System dual modular mixed metal junctions and metal-on-metal articular surfaces were defective for the reasons described herein, and Defendants had the opportunity and duty to warn surgeons and Plaintiff of the defective nature of the Wright Total Hip System.

139. Defendants' conduct, as described above, including, but not limited to, their failure to adequately test and warn, as well as their continued marketing and distribution of the Wright Total Hip System when they knew or should have known of the serious health risks these devices created and/or the failure to comply with federal requirements, was and is negligent.

140. As a direct, legal, proximate and producing result of the Defendants' negligent design, testing, manufacturing, marketing selling and promoting the Wright Total Hip System, Plaintiff LARRY HALL was injured.

141. Defendants' negligent design, testing, manufacturing, marketing, selling and promoting of the Wright Total Hip System implanted in Plaintiff LARRY HALL was a substantial factor in LARRY HALL's injuries as set forth above.

WHEREFORE, Plaintiff LARRY HALL demands judgment against the Defendants, in an amount in excess of the minimum jurisdictional limits of this Court, costs and further demands trial by jury.

FIFTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

142. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs, 1-93, and further alleges as follows:

143. In the exercise of reasonable care, Defendants should have known that the Wright Total Hip System failed to comply with federal requirements for safe design and manufacture and/or was in other ways out of specification, yet they negligently misrepresented to Plaintiff

LARRY HALL and/or his physicians that their device was safe and met all applicable design and manufacturing requirements.

144. Defendants made misrepresentations and material omissions in their marketing, advertisements, promotions and labeling concerning these products for use in patients such as Plaintiff LARRY HALL.

145. Plaintiff LARRY HALL and/or his physicians justifiably relied to their detriment upon Defendants' misrepresentations and omissions in their marketing, advertisements, promotions and labeling concerning these products.

146. Plaintiff LARRY HALL and/or his physicians justifiably relied upon Defendants' representations that the Wright Total Hip System was safe for use in persons such as Plaintiff LARRY HALL.

147. Defendants had a duty to truthfully represent to the medical community, and to Plaintiff LARRY HALL's healthcare providers and the FDA, that the Wright Total Hip System had been properly tested and found to be safe and effective for its intended use.

148. Defendants knew or should have known the representations regarding the safety and performance of the Wright Total Hip System were in fact, false.

149. Defendants failed to exercise ordinary care in determining the truth or falsity of their representations, and by misrepresenting the safety and performance of the Wright Total Hip System.

150. Defendants breached their duty to present truthful representations by knowingly, or by want of ordinary care, misrepresenting the safety and performance of the Wright Total Hip System.

WHEREFORE, Plaintiff LARRY HALL demands judgment against the Defendants, in

an amount in excess of the minimum jurisdictional limits of this Court, costs and further demands trial by jury.

SIXTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

151. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs, 1-93, and further alleges as follows:

152. Defendants Wright expressly warranted that the Wright Total Hip System devices were safe and effective orthopedic devices for those patients requiring a hip replacement.

153. The Wright Total Hip System devices manufactured and sold by Defendants Wright did not conform to these express representations because they caused serious injury to Plaintiff when used as recommended and directed.

154. As a direct and proximate result of Defendants Wright's breach of warranty, Plaintiff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff LARRY HALL demands judgment against the Defendants, in an amount in excess of the minimum jurisdictional limits of this Court, costs and further demands trial by jury.

SEVENTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

155. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs, 1-93, and further alleges as follows:

156. At the time Defendants Wright designed, manufactured, marketed, sold, and distributed the Wright Total Hip System devices for use by Plaintiff, Defendants Wright knew of the use for which these devices were intended and impliedly warranted these products to be of

merchantable quality and safe for such use and that their design, manufacture, labeling, and marketing complied with all applicable federal requirements.

157. Plaintiff and and/or his physicians reasonably relied upon the skill and judgment of Defendants Wright as to whether the Wright Total Hip System devices were of merchantable quality and safe for their intended use and upon Defendants Wright's implied warranty as to such matters, including that they were in compliance with all federal requirements.

158. Contrary to such implied warranty, Defendants Wright's devices were not of merchantable quality or safe for their intended use, because the products were defective as described above, and/or failed to comply with federal requirements.

159. As a direct and proximate result of Defendants Wright's breach of warranty, Plaintiff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff LARRY HALL demands judgment against the Defendants, in an amount in excess of the minimum jurisdictional limits of this Court, costs and further demands trial by jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff LARRY HALL prays for judgment against the Defendants WRIGHT MEDICAL TECHNOLOGY, INC., jointly and severally, as follows:

a. Compensatory damages, in excess of the amount required for federal diversity jurisdiction, and in an amount to fully compensate Plaintiff for all his injuries and damages, both past and present;

b. Special damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all of his

injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, lost income, permanent disability, including permanent instability and loss of balance, and pain and suffering.

c. Double or triple damages as allowed by law;

d. Attorneys' fees, expenses, and costs of this action;

e. Pre-judgment and post-judgment interest in the maximum amount allowed by law;

f. Punitive damages; and,

g. Such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiff LARRY HALL demands a trial by jury on all issues and matters so triable by jury as a matter of right.

Dated: April 17, 2020

/s/ Justin A. Browne
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